MedSun: Newsletter #39, August 2009

Articles

Abbott Issues Voluntary Recall of POWERSAIL Coronary Dilatation Catheters

Print Item
E–mail Item

Recall - Firm Press Release

Abbott has conducted a voluntary recall of three lots of POWERSAIL Coronary Dilatation Catheters from United States distribution and one lot from international distribution as a result of four complaints (one from each lot) that the distal shaft of the catheter exhibited damage. While the issue could be detected and avoided during the preparation for use of the product, it may cause a leak of contrast material during use, which could lead to catheter functional failures and clinical consequences, including air embolism and myocardial infarction, which has the potential to lead to death.

Additional Information:

Recall – Firm Press Release. Abbott Issues Voluntary Recall of POWERSAIL® Coronary Dilatation Catheters. July 30, 2009.
http://www.fda.gov/Safety/Recalls/ucm174429.htm[7]

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BiPAP Focus Non-Invasive Ventilator System, Respironics California

Print Item
E–mail Item

FDA Recall Notice

Respironics California, Inc. and FDA notified healthcare professionals of a Class I recall of the BiPAP Focus Non-Invasive Ventilator System, model number PCM120PS18-2315P. This device is used by healthcare professionals to treat adult patients who have advanced lung disease and/or have difficulty breathing. Power supply failures have occurred on some ventilators.

Additional Information:

FDA MedWatch Safety Alert. BiPAP Focus Non-Invasive Ventilator System, Respironics California. July 9, 2009.
www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm171242.htm[9]

FDA CDRH Recall Notice. Respironics California Inc., BiPAP Focus Non-Invasive Ventilator System. July 9, 2009.
http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm171194.htm[10]

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Medtronic Paradigm Quick-Set Infusion Sets

Print Item
E–mail Item

FDA Recall Notice

Medtronic, Inc. and FDA notified healthcare professionals and patients of a recall of Quick-set infusion sets that are used with MiniMed Paradigm insulin pumps because the affected infusion sets may not allow the insulin pump to vent air pressure properly. This could potentially result in the device delivering too much or too little insulin and may lead to serious injury or death.

Additional Information:

FDA MedWatch Safety Alert. Medtronic Paradigm Quick-Set Infusion Sets. July 13, 2009.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm171686.htm[12]

Medtronic Press Release. Medtronic Voluntarily Recalls Specific Lots of Paradigm® Quick-Set® Infusion Sets In The United States. July 21, 2009.
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm171588.htm[13]

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Looking Into Problems With Transvaginal Surgical Mesh

Print Item
E–mail Item

By Nasrin Mirsaidi, RN, CNOR, MSN

Transvaginal placement of mesh has become increasingly popular in recent years. However, in the last 3 years, the FDA has received over 1,000 adverse event reports about mesh used in transvaginal surgical repair of pelvic organ prolapse and stress urinary incontinence. Although the exact cause of these adverse events hasn't been identified, they're likely to be the result of multiple factors. This article provides precautions for healthcare professionals when performing this procedure.

Additional Information:

FDA Medical Device Safety website. Looking into Problems with Transvaginal Surgical Mesh. By Nasrin Mirsaidi, RN, CNOR, MSN. July 2009.

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm169802.htm[15]

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Reduce the Risk of Skin Burns

Print Item
E–mail Item

By Nasrin Mirsaidi, RN, CNOR, MSN

This article discusses light induced skin burns related to surgical microscopes. Despite many safety features, surgical microscope-induced injuries still occur and technological means to eradicate these adverse events are yet to be developed. For example, an infant's thin skin or an elderly patient's fragile and dry skin is at greater risk. In addition, the patient's tissue perfusion must be considered.

Additional Information:

FDA Medical Device Safety website. Reduce the Risk of Skin Burns. By Nasrin Mirsaidi, RN, CNOR, MSN. July 2009.
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm169604.htm[17]

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Tips to Remember When a Medical Device Adverse Event Happens

Print Item
E–mail Item

(Excerpted with permission from the University of Michigan Health System Risk Management Handbook 2008)
Jahan Azizi, Clinical Engineer for Risk Management, U. of Mich. Hosp. Sys, Bill Riemenschneider and Suzanne Rich, MedSun

After assessing the safety and well-being of the patient, patient's visitors, and staff:

• If a patient or staff is involved, notify the patient's physician(s), your manager or supervisor, and Risk Management, according to your facility's protocol.
• Don't unplug or turn off equipment unless it poses a danger to the patient – unplugging or turning off devices can cause important or useful stored data to be lost. This data is often critical to understanding what happened.
• Submit a report, according to your hospital's policy and procedure (e.g., via phone, online, or by submitting a hardcopy incident event report).

1. State exactly what happened during the event by documenting all details related to the event. Include in your event assessment:

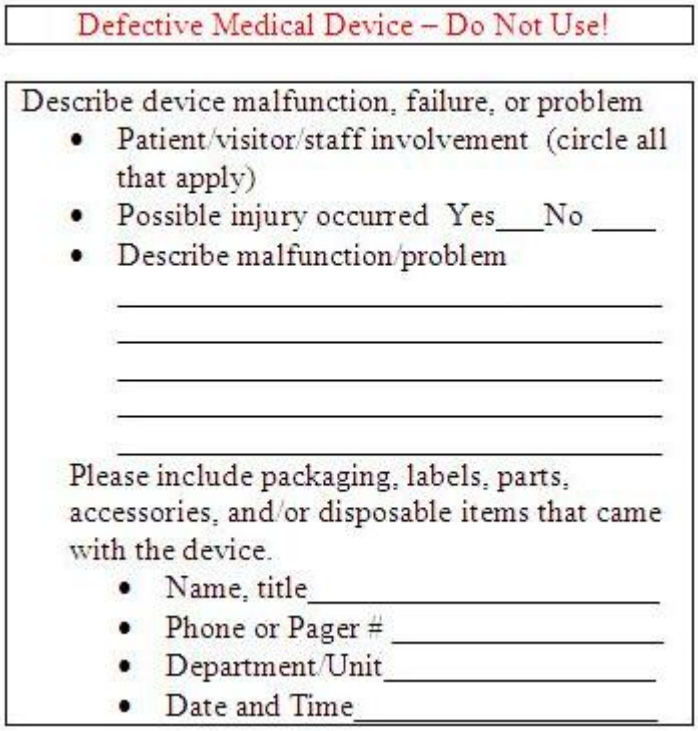
• Actions taken to address the situation, including notification of primary care providers and nursing, biomedical and risk management supervisors as appropriate.
• Any associated injuries to the patient, visitors, or staff, follow-up care taken, and outcome.
• Provide information on the types of tests that were done to mitigate the effects of the event. Don't include tests that were done as a part of the patient's original treatment.
• For example, if an X-ray was taken in order to locate a fragment of a broken device.
• If a biomedical staff person or manufacturer's service representative performed an analysis of a failed instrument, provide the date and time of the analysis and the results.

2. Provide device identifier information including manufacturer, brand, model, lot and serial number information if available. If the event involves a disposable device that was discarded, obtain device identifier information from product in stock.

• Provide device identifier information for the whole "device system". For example, a report describing erroneous readings from a pulse oximeter may need to include information on the monitor and cables used with the pulse oximeter if it isn't clear the problem is strictly with the finger sensor.

Save and Tag the medical devices and equipment involved, including disposable items and packaging (e.g., foley catheters, IV pumps and tubing, etc.).

1. Use your facility's tag or use the sample below as a critical safety step to prevent further use of the device or equipment on a patient.
2. Sequestering the devices and equipment provides for evaluation by biomedical or clinical engineering or by the manufacturer and preserves historical data helpful to understanding the role of the device in the event.



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Safety in the MR Environment: Ferromagnetic Projectile Objects in the MRI Scanner Room

Print Item
E–mail Item

Pennsylvania Patient Safety Advisory

Between June 2004 and December 2008, the Pennsylvania Patient Safety Authority received 27 reports of objects becoming projectiles in the MR environment, 16 ferromagnetic items that were brought into the MRI scanner room without becoming projectiles, and 5 ferromagnetic items almost allowed into the MRI scanner room. Proper MR screening practices for ferromagnetic items and establishing protocols for identifying and labeling equipment that can and cannot be brought into the scanner room will help reduce the risk of objects becoming projectiles within the MR environment.

Additional Information:

Pennsylvania Patient Safety Advisory. Safety in the MR Environment: Ferromagnetic Projectile Objects in the MRI Scanner Room. June 2009. http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Jun6(2)/Pages/56.aspx[20]

FDA Medical Device Safety page. MRI Safety. June 25, 2009. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm135362.htm[21]

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Quarterly Beyond the Count: Preventing the Retention of Foreign Objects

Print Item
E–mail Item

Pennsylvania Patient Safety Advisory

The retention of a foreign object may cause serious patient harm and often requires further medical treatment. Surgeons and operating teams routinely rely on the practice of a sponge, sharp, and instrument count to reduce the risk of a retained foreign object. However, counting alone may be insufficient. This article examines risk factors for retained foreign objects following surgery and addresses the role of human factors analysis to uncover system vulnerabilities. Risk reduction strategies include improved perioperative processes, perioperative team communication, and the use of assistive technology.

Additional Information:

Pennsylvania Patient Safety Advisory. Quarterly Beyond the Count: Preventing the Retention of Foreign Objects June 2009.
http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Jun6(2)/Pages/39.aspx[23]

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Uterine Perforation Associated with Minimally Invasive Gynecologic Procedures

Print Item
E–mail Item

Pennsylvania Patient Safety Advisory

Dilation and curettage, dilation and evacuation, and hysteroscopy are three minimally invasive gynecologic procedures that are performed to diagnose and treat various female pelvic health conditions. Studies show that these procedures have relatively low complication rates and can be performed safely in multiple clinical settings. The predominant complication reported is perforation of an organ, most frequently the uterus (96%). Risk reduction strategies employed to decrease the incidence of uterine perforation involve conducting a thorough pre-procedure evaluation to identify any predisposing factors, preparing the cervix for the procedure, and using careful cervical/uterine entry techniques.

Additional Information:

Pennsylvania Patient Safety Advisory. Uterine Perforation Associated with Minimally Invasive Gynecologic Procedures. June 2009.
http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Jun6(2)/Pages/51.aspx[25]

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LabNet

Ethics Code Changes for Diagnostics Manufacturers, Clinical Laboratory News Why Should Laboratories take Notice

Print Item
E–mail Item

American Association for Clinical Chemistry (AACC)

The revised AdvaMed (Advanced Medical Technology Association) Code of Ethics which went into effect July 1, 2009, is intended to help IVD and other medical device companies avoid inappropriate activity in their relationships with healthcare professionals. The code further clarifies and distinguishes between appropriate and inappropriate activity between health care professionals and representatives of AdvaMed member companies, which include diagnostics manufacturers and medical device manufacturers. Highlights of the revised code are included in the full article.

Additional Information:

Ethics Code Changes for Diagnostics Manufacturers, Clinical Laboratory News Why Should Laboratories take Notice. Malone, Bill. American Association for Clinical Chemistry (AACC). June 2009.
http://www.aacc.org/publications/cln/2009/June/Pages/CovStory2June09.aspx[27]

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HomeNet

Make Sure the Medical Device You Choose Is Designed for You

Print Item
E–mail Item

FDA Device Regulation and Guidance

This checklist is designed for health care professionals and patients to use when choosing the best medical device to meet patients' needs. When selecting a device, it is important to consider how the environment and how the users capabilities may contribute to the safety and effectiveness of a device.

Additional Information:

Make Sure the Medical Device You Choose Is Designed for You. FDA Device Regulation and Guidance. July 18, 2000.

[29]

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/HumanFactors/ucm128206.pdf[30]

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KidNet

Draeger Initiates a Voluntary Device Recall of Stabilet: Contacts Current Users

Print Item
E–mail Item

Recall - Firm Press Release

Draeger Medical and FDA notified healthcare professionals that it recommends the removal of Stabilet Infant Warmer models 200, 300, 1250, 1500, 200/3000, 2000, 2200/3200, 3000, and 3200 from service as soon as possible due to concern that continued use of these devices may result in serious injury to the patient and/or caregiver.

Additional Information:

Recall – Firm Press Release. Dräger Initiates a Voluntary Device Recall of Stabilet: Contacts Current Users. July 20, 2009.
http://www.fda.gov/Safety/Recalls/ucm172783.htm[32]

Firm Recall Notice. Dräger Initiates a Voluntary Device Recall of Stabilet: Contacts Current Users. July 20, 2009.
[33]

http://www.draeger.com/media/10/03/20/10032012/pr_090720_43us_stabilet.pdf[34]

FDA MedWatch Safety Alert. Stabilet Infant Warmer models 200, 300, 1250, 1500, 200/3000, 2000, 2200/3200, 3000, and 3200 [Dräeger/Hill-Rom]. July 20, 2009.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm173239.htm[35]

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Highlighted MedSun Reports

Highlighted Reports

Print Item
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This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during the period May 1 through May 30. All other reports can be searched under the 'MedSun reports' menu pane. Note: the two month delay is due to quality control and follow-up.

ORTHOPEDIC

Device:
Type: Shaver, Arthroscopic
Manufacturer: Stryker Endoscopy
Brand: Formula 180 Shaver Handpiece
Lot #: 375-708-500
Cat #: 375-708-500

Problem:

Following manufacturer recommended cleaning and sterilization procedures, an internal scope examination of multiple Stryker shavers revealed human tissue debris within the body section of the devices.

Comment from FDA: Please see FDA communication, "Ongoing Safety Review of Arthroscopic Shavers" online available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=38#1

Device:
Type: Hip Femoral Head
Manufacturer: Wright Medical Technology, Inc
Brand: Conserve Total A-class Head W/bfh Technology Short Neck
Model #: label stated # 36mm OD short neck
Lot #: label stated # 029798201
Cat #: label stated # 38AM-3604

Problem:

This was a planned total hip implant procedure. When the femoral head from Wright Medical was opened, it was observed that the wrong implant was in the package. Surgeon had requested a 36mm short. The package label stated 36mm OD Short Neck, and the inside label said the same thing, 36mm OD Short Neck. When the surgeon looked at the device on the sterile field, it did not look correct. It was observed that the actual stamped

information on the implant itself said 36mm Long.

GENERAL & PLASTIC SURGERY

Device:
Type: Fixation Device
Manufacturer: Covidien United States Surgical Corporation
Brand: Protack
Cat #: 174006

Problem:

The ProTack instrument from Autosuture should never be used in closing hernia defect in and about the diaphragm. The use of the tacks on the diaphragm can result in episodic cardiac injury leading to cardiac tamponade and premature demise of a patient. This injury can be challenging to find and confound attempts to alleviate progressive decline of a patient's condition. This injury can occur months or years after they are placed. A surgeon's recommendation is to prohibit the future use of the ProTack Autosuture instrument in repairing diaphragmatic hiatal hernias.

Device 1:
Type: Prep Solution
Manufacturer: 3M Healthcare
Brand: Duraprep
Lot #: 2012-02AJ1
Cat #: 8630
Other #: NDC: 17518-011-08

Device 2:
Type: Drape, Antimicrobial
Manufacturer: 3M Healthcare
Brand: Ioban 2
Lot #: 2011-02 CD
Cat #: 6640EZ
Other #: 34-8701-3137-1

Device 3:
Type: Drape, Antimicrobial
Manufacturer: 3M Health Care

Problem:

Patient with intact skin underwent surgical prep with Duraprep for foot surgery. Ioban steri-drape placed over prepped skin. When steri-drape attempted to be removed after the

initial portion of the procedure, patient's skin was blistered and peeled off with the steri-drape. When the foot was examined, additional areas on the foot blistered where Duraprep was used. The procedure was terminated at that point. 3M Remover Lotion was used by the surgeon to gently remove the remaining Duraprep from the patient's skin. Dorsal foot with denuded area. Large toe and sole of foot with denuded areas.

Device:
Type: Wound Therapy Device
Manufacturer: KCI
Brand: Infovac
Model #: 60090

Problem:

RN reports Wound Vac error message "container full", but container was not full. RN reset, error message then reading "container not engaged", troubleshooting guide followed, still reading "not engaged", container changed, no results, machine changed completely and began working immediately. No impact to patient. Device is a rented machine so will be returned to vendor for evaluation.

Device 1:
Type: Endoscopic Vein Harvesting System
Manufacturer: Terumo Cardiovascular Systems Corp.
Brand: Virtuosaph
Model #: Ref # MCVS550
Lot #: 8YK
Other #: PK # 8056741

Device 2:
Type: Endoscopic Vein Harvesting System
Manufacturer: Terumo Cardiovascular Systems Corp.
Brand: Virtuosaph
Model #: Ref # MCVS550
Lot #: 8YK
Other #: PK # 8055467

Problem:

When performing endoscopic vein harvesting, the bipolar/cutting feature was not working. An additional device was opened and also did not work. Third device worked properly - no patient harm.

Device:

Type: Surgical Blade
Manufacturer: BD
Brand: Bd Bard Protected Blade System
Model #: 11
Lot #: 8162706
Cat #: 373911

Problem:

Patient with a history of chronic pelvic pain was undergoing laparoscopy using an open technique - lysis of extensive adhesions in the left upper quadrant and right upper quadrant and lysis of pelvic adhesions. Physician went through three Bard-Parker # 11 blades before she could find one sharp enough to make an incision.

Device:
Type: Hemostatic Matrix
Manufacturer: Baxter International
Brand: Floseal Hemostatic Matrix
Lot #: HA081229
Problem:

Floseal was needed to control bleeding during surgical procedure. The product box is labeled STERILE with notation, "Unless opened or damaged, contents are sterile." Box containing items to be used is not sealed in sterile packaging.

Product box opened by circulating nurse and contents removed by sterile-gloved scrub tech and placed on the sterile field. Contents of the box included gelatin matrix component that is in a closed sterile package, 2 vials; human Thrombin and calcium chloride, and a 5ml syringe inside a sealed package.

The non-sterile packages removed from the box were placed onto the sterile field. The sterile field was unknowingly contaminated. The labeling on the box that noted that the contents were sterile unless opened or damaged confused the staff opening the product for use.
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Manufacturer response for hemostatic Matrix, Floseal Hemostatic Matrix
==========
The manufacturer has acknowledged the information and will be investigating.

RADIOLOGY

Device:
Type: Transducer, Ultrasound, Transesophageal Echocardiograph

Manufacturer: Toshiba America Medical Systems, Inc.
Brand: Toshiba
Model #: PET- 511BTM

Problem:

The patient was undergoing a Trans-Esophageal Echo Cardiogram when the TEE scope buckled.

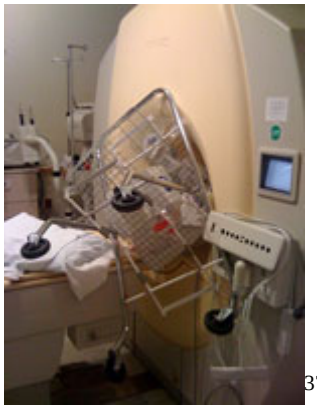
Device:
Type: Mri, 1. 5t
Manufacturer: Philips Medical Systems
Brand: Philips Achieva

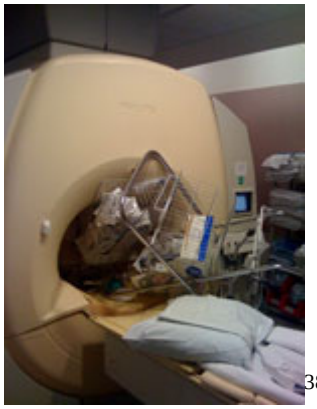
Problem:

IV nurse entered MRI suite and brought her metal IV cart halfway in doorway of MRI suite. The force of the MRI magnet caused the IV cart to lift up and it flew through the air, on to the MRI machine. Patient was lying outside of the MRI, on the MRI table at the time. The cart did not hit him. Another Nurse was on right side of patient and was looking for venous access in his right arm at the time of the incident. She was not injured. No injury for any individual - lots of potential for injury!

The IV nurse had been called to access the patient located in MRI. She did not realize the power of the MRI magnet especially when the patient was not in the MRI. She intended to leave the cart at the door, but should not have entered the room.

This is being reported not because of a device malfunction but as an alert of an incident regarding an MRI and need for better vigilance and perhaps education regarding the fact that MRI magnets are ALWAYS on and the need for better safety.

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Device:
Type: Catheter, Brachytherapy, Intracavity, Icrt
Manufacturer: Best Vascular, Inc.
Brand: Novoste Betacath System
Lot #: Beta-Cath 3.5R System
Problem:

Novoste BetaCath System: the ICRT catheter was kinked so the Sr-90 radioactive train could not be sent back to the device. After the treatment was finished, MD tied to push the Sr-90 radioactive source back to the device; the source left the treatment area and was stuck in the catheter junction outside of the patient's body. MD said the catheter had a kink at the junction. The catheter was pulled out from the patient's body and dumped in a shielded transportation box with whole device. The patient and room was surveyed using radiation survey meter. No radiation was found inside the patient body and in the treatment room of the cardiac cath lab.

Device:
Type: Ct Scanner
Manufacturer: Siemens Medical Solutions USA, Inc.
Brand: Somatom Definition As +

Problem:

Operator attempted to tilt by 2 degrees the CT gantry to perform a sinus scan study. A ticking sound followed by a banging noise was heard prior to the CT cover cowl separating from the machine, falling on the patient's back and arm, and then falling to the floor. This occurred within approximately 14 seconds.

The gantry cover was not secured properly and it opened. The cover cowl was forced off by the moving gantry mass and it fell onto the patient.

MICROBIOLOGY

Device:
Type: Lab Reagent Kit
Manufacturer: Becton Dickinson
Brand: B-d Directigen Ez Kit For Rsv Rapid Antigen
Lot #: 8296111, 8330466, 8296126
Cat #: B694410
Problem:

Respiratory Syncytial Virus (RSV) rapid antigen assays were ordered on patients on two consecutive days. After thirteen results were reported positive using the Becton Dickinson Directigen EZ kits, the director was notified as well as the Medical Director of Hospital Epidemiology & Infection Control. RSV antigen assays were followed up with PCR and culture for confirmation. BD Technical services were notified and a conference call followed three days after the reported positive results. We had a total of seventeen positives and all seventeen were false positives.

BD Scientific group came to our lab ten days later following the conference call to run the samples to see if they could determine the problem. Lot numbers included 8296111, 8330466 and 829126. Awaiting BD's evaluation of the problem.

NEUROLOGY

Device:
Type: Electromyograph, Diagnostic
Manufacturer: Cadwell Laboratories
Brand: Cadwell Cascade
Model #: ES-5-100
Cat #: 190221-200
Problem:

30 minutes after starting the machine, a burning smell was noticed when attaching lead wires to the ES-5-100 stimulator box. The unit was immediately removed from service. The stimulator box was connected to a Cadwell Cascade Elite. Later investigation revealed the inside of the stimulator box was extensively burned and the case was partially melted. The concern here is this device was located under the surgical drape near the patient's foot and if a flame had protruded, it would set the drape on fire. There was a minor delay while the stimulator box was replaced. There was no harm to the patient.

There was a fairly large section of the circuit board that was charred and it is likely that there was a small flame inside the box at one point. Coincidentally, a second stimulator box in a different room failed on the same day, but not as extensively burned. According to the manufacturer, if the clinicians accidently plug the stimulator box into the wrong port (aux. port) on the main unit, this kind of burning failure is common. Apparently, if

the clinician even plugs it in for a brief time, it will damage components and cause failure. The plugs are similar to standard computer VGA video connectors with one pin hole blocked and a corresponding missing pin on the plug to act as a key against misconnection. Close examination of the socket on the main unit revealed that the key plug was missing on one of the aux. connectors making it possible to misconnect easily. Clinicians report that it would be highly unlikely that the cable was misconnected. Another possibility is the cable that goes from the main unit to the stimulator may have been damaged by other equipment rolling over it, causing a short, but the cables tested OK.


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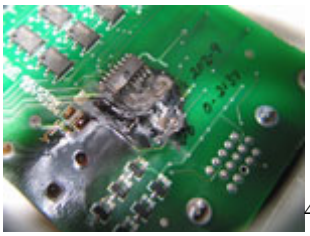
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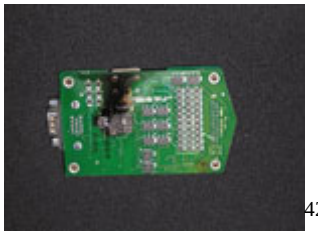
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GENERAL HOSPITAL

Device:
Type: Iv Tubing
Manufacturer: B. Braun Medical, Inc.
Brand: Ultrasite
Model #: 470042
Lot #: 0061014595, 0061050990
Cat #: US1504HP
Other #: 4 from - Lot #: 0061014595 exp 08/11 and 2 from lot # 0061050990 02/12

Problem:

RN reports 6 sets of defective tubing over various dates. None of the tubing sets were actually used on patients. The issue was identified before use. In all cases fluid would not run through the tubing. All devices were retained and are available for evaluation purposes. There was no damage noted to the tubing upon visual inspection. Similar issues with this tubing have been experienced by our facility in the past, and previous inspections by B. Braun of the tubing from those reports indicated that there was too much solvent in the manifolds.

Device:
Type: Infusion Pump
Manufacturer: ALARIS Medical Systems, Inc.
Brand: 8100 Pump Module
Model #: 8100

Problem:

Upon powering up a module to begin an infusion on a patient, the module continually beeped “channel malfunction.” The channel malfunction warning indicator was on prior to connecting to the patient. A patient was not involved with this IV pump malfunction.

Biomed Assessment: The channel error alarm was caused by a defective upper pressure sensor. The sensor was replaced with a new one at no charge. After repair, the unit passed the manufacturer's test procedure and was returned to use.

Comment from FDA: See Alaris Recall online available at http://www.cardinalhealth.com/alaris/medical-device-recall/

Device:
Type: Pca Pump
Manufacturer: Hospira Global Medical Affairs

Brand: Gemstar
Model #: version 4.30

Problem:

The RN discovered that the PCA pump settings were different than what they had been previously when she checked on the patient. Staff was interviewed and had not changed the pump. Two staff members had been present when the new bag of Dilaudid was placed in the PCA pump, but the settings were different from what the RN discovered upon entry to the room. The patient denied altering the pump. However, a download of the pump showed that the settings had been changed twice - once earlier in the shift and then changed back to the MD's ordered settings and then again when the RN discovered different settings on the pump. The staff had also witnessed the patient manipulating the pump.

Anesthesia was notified and discontinued the PCA pump. The patient was changed to oral pain medications for pain control. Biomed checked the pump and it was functioning appropriately. It was deduced that the patient had learned the code to access the pump and was able to change the settings to bolus himself.

As a result of this event, the hospital changed the code from a 3 digit to a 5 digit non-sequential code. Education was provided to nursing staff so that when the code is entered into the machine, the RN turns the pump away from the patient's line of sight. The patient has since returned to the facility and has not been able to access the pump's settings.

Device:
Type: Iv Tubing
Manufacturer: ALARIS Medical Systems, Inc.
Brand: Alaris Burette Set
Lot #: 08035469
Cat #: 10779313

Problem:

A new TPN bag was primed for use, and was started on a patient. Approximately 4.5 hours later, the TPN was found on the floor near the pump. The pump did not alarm. The TPN tubing was attached to the patient with no visible air bubbles. When the tubing was removed from the pump, the TPN leaked from the part of the tubing that fits into top portion of the cassette.

Device:
Type: Pca Pump And Pcea Volume Infuser
Manufacturer: Hospira Global Medical Affairs
Brand: Gemstar

Model #: CE0050

Problem:

Our facility recently changed to a new lockbox product for PCA and PCEA (Patient Controlled Epidural Analgesia) volume infusers. Because of the new configuration of the lockbox, the way that the PCA and PCEA tubing is threaded through the Gemstar PCA and PCEA devices is different. If the IV tubing is threaded incorrectly, the tubing will be pinched and the device will not run properly. However, it is not intuitive to the nursing staff where the tubing should be threaded.

Staff suggested that it would be helpful if the Gemstar manufacturer could place an arrow with the phrase "thread here" on the device. In the interim, a sticker was created and placed on the device to indicate how it should be threaded. Additionally, staff has received education regarding how to thread the device with the new lock-boxes.

The manufacturer was notified and has provided a sticker template with directions for threading the device.

Device:
Type: Bottle, Collection, Vacuum
Manufacturer: Cardinal Health
Brand: Safe TCentesis
Lot #: L9C312F

Problem:

Safe T Centesis 6 fr. Cath drainage tray noted to have an air leak in the Y connector that connects tubing to drainage bottle – one way valve not working – no vacuum achieved.

Trays were pulled off the shelves, reported and returned to cardinal health. Cardinal health stated they had received no other reports of problems with this product. A new shipment was received 6 days later.

A second event occurred 9 days after first event. An air leak was again noted when the tubing was connected to the drainage bottle. The physician performing the procedure also noted that the scalpel in the tray was not sharp. Upon investigation, it was found that the new shipment was the same lot # that had previously been pulled and returned to cardinal health. Trays from the affected lot number have been pulled from all units pending further investigation.

Health professional's impression:
No adverse event reached the patient. The air leak was noted during the procedure and a different set was utilized.
==========

Manufacturer response for Chest tube system, Safe T Centesis
==========
States they have received no other reports of problems with the device.

Device:
Type: Syringe, Antistick
Manufacturer: Retractable Technologies
Brand: Vanishpoint Syringe
Cat #: 10301
Other #: 100301 (syringe - 3 cc)

Problem:

Retractable needle did not retract. This is not the first event of this happening with these needles. No patient injury.

Device:
Type: Infusion Pump
Manufacturer: ALARIS Medical Systems, Inc.
Brand: Medsystems Iii

Problem:

A patient was being transported into a medical helicopter for transport to another hospital, when the Alaris IV pump failed. The pump was infusing Norepinephrine when it "locked out," and would not pump. The pump was reporting "channel not available." Another channel was selected, and the pump again indicated "channel not available." The patient was quickly brought back into the hospital's ICU, placed on a different IV pump, and reassessed. After clearance, the patient was taken to the helicopter and transferred to another hospital. The pump in question was immediately removed from service and sent to our Clinical Engineering department for analysis.

Device:
Type: Mattress, Flotation Therapy, Non-powered
Manufacturer: Kinetic Concepts, Inc.
Brand: First Step Select

Problem:

The elderly patient was identified as being at high risk for development of pressure ulcers and so as part of the pressure ulcer prevention protocol, the patient was placed on a First Step Select overlay mattress. Three days after placement of the mattress, a nurse was in the hallway outside of the patient's room and heard a noise come from the patient room.

The nurse found the patient lying on the floor. The patient reported; was "trying to use the urinal and slid out of the bed onto the floor." The patient had no apparent injuries from the fall.

The overlay mattress has an air-filled chamber portion and a cover. Both of these items are made of a nylon-like material. This combination of slippery surfaces does have a "slip and slide" effect. The mattress overlay base is to be strapped to the frame of the bed by Velcro straps and the cover is to be tucked under the air mattress. Care is also taken to use the Hill Rom 840 bed instead of the Hill Rom Versa Care bed as the Versa Care beds do not have enough height to the side rails and a patient could easily go over the side rails due to the thickness of the overlay mattress. In this particular case, the patient was on a 840 bed and the nurse discovered that the mattress overlay was not anchored to the bed frame and the cover was not tucked in.

It is normally the practice for KCI to set up these mattresses, but not always. KCI will be contacted regarding this problem. Staff on the nursing unit on which this occurred noted that they have been using these mattresses for years and this is the first time they have encountered an overlay mattress that was not anchored properly to the bed frame.

Device 1:
Type: Iv Set
Manufacturer: Carmel Pharma Inc.
Brand: Phaseal Injector Luer Lock
Cat #: N31

Device 2:
Type: Iv Set
Manufacturer: Carmel Pharma Inc.
Brand: Phaseal Connector Luer Lock
Cat #: C40

Problem:

The patient bumped his infusion pump while walking through a doorway in the patient lounge. This caused the PhaSeal system to loosen because it extends out slightly from the infusion pump. Small drips of chemotherapy dripped on the floor, and some nurses noticed a small pool of chemotherapy when the patient stopped walking. A chemotherapy spill kit was obtained, and housekeeping was notified. The spill was contained. Patients and families were notified to stay out of the lounge and the small hallway. There was no patient injury. The PhaSeal Connector sticks out from the side of the pump and has contributed to disconnections and chemo spills in the past.

Device:
Type: Infusor, Pressure, For I. V. Bags

Manufacturer: Vital Signs
Brand: Infusable Pressure Infusor
Other #: Ref # IN8000

Problem:

Pressure bag pumped up to correct pressure; netting holding 500 cc bag ripped along side of bag. Pressure bag had to be replaced. No patient harm.

Additional information obtained from the site:
There was no patient harm, they just switched bags. There have been 3 more similar incidents before. The packaging was not saved, so there is no lot number available.

Device:
Type: Catheter, Intravascular, Therapeutic, Short-term
Manufacturer: Becton Dickinson
Brand: Bd Insyte Autoguard
Model #: 18 ga 1.16 in, 1.3 X 30mm
Lot #: 7340858
Cat #: ref 381444

Problem:
Nurse was attempting to place an 18 gauge intravenous catheter (IV start) into a Labor & Delivery patient's vein in left forearm. Nurse entered the patient's vein with the catheter and when attempting to advance the catheter, the hub broke off from the plastic angio. Fortunately the nurse was able to remove the catheter. Potential for detached catheter to have entered patient's vein.

Device:
Type: Tubing, Infusion
Manufacturer: ALARIS Medical Systems, Inc.
Brand: Alaris Se Pump Administration Set
Cat #: C72106M

Problem:

The infusion pump was programmed to infuse at 66 ml per hour. The potassium chloride infused the total amount in 15 minutes. Upon biomedical department investigation, the backflow preventer on the primary tubing set was not operating correctly. Approximately 6.5 ml of the potassium chloride secondary infusion was delivered to the patient, and the remaining fluid emptied into the primary bag.

ANESTHESIOLOGY

Device:

Type: Endotracheal Tube
Manufacturer: Mallinckrodt
Brand: Intermediate Hi-lo
Lot #: 081200 1153
Cat #: 86450

Problem:

Anesthesiologist intubated a patient for cardiac surgery and while taping the endotracheal tube in place outside the patient's mouth he noted an airway leak. He added more air via syringe to the tube cuff but again noted an airway leak. When he went to examine the pilot balloon (a small, in-line balloon that shows that the cuff/tubing/luer valve system is pressurized), he noticed that it had become disconnected from the cuff tubing. Close examination of the cut end shows repeated striations to the material like what would be obtained with a sawing motion.

Device:
Type: Anesthesia Breathing Circuit
Manufacturer: Medline Industries
Brand: Circuit, Adult Anesthesia
Model #: DYNJAA9832D
Lot #: 08LB2281
Cat #: DYNJAA9832D

Problem:

During the induction phase prior to surgery, the Anesthesiologist noticed that the 90 degree respiratory gas sample elbow "popped" off the parallel “wye” section of the patient circuit. The doctor tried to reattach the elbow, but the fit was very loose. The doctor obtained a different style sample gas elbow and it secured properly. The doctor noted this same problem with several patient circuits and notified the manufacturer to exchange all the patient circuits with this model and lot number.
==========
Manufacturer response for Anesthesia breathing circuit, Circuit, Adult Anesthesia
==========
Manufacturer replaced all the patient circuits with different circuit set.

Device:
Type: Anesthesia Unit
Manufacturer: GE Medical Systems, LLC
Brand: Datex Ohmeda S/5
Model #: AAUFO2

Problem:

Gas monitoring problems detected. On the display showing gas information, the displayed numbers went blank intermittently. No patient harm.

Biomedical engineering was contacted and worked with the manufacturer to perform a factory reset. The reset involved clearing the anesthesia unit's memory, then reloading all the default information and checking for proper operation. The reset did not correct the problem, as it recurred as an intermittent problem thirteen days later. At that time, the factory service technician, working with our Biomed department, replaced the display and the circuit board which feeds the gas information to the display. The problem has not returned since.

Device:
Type: Universal Neonatal Heated Ventilator Breathing Circuit
Manufacturer: Teleflex Medical Incorporated
Brand: Hudson Rci
Model #: Ref. 780-09
Lot #: 02324
Cat #: 02L08
Other #: Humidifier Unit, Model: concha Therm

Problem:

The far end of the inspiratory breathing limb was missing an additional temperature probe Tee connector. The second temperature probe was connected to the Y port. The inspiratory breathing limb touched the expiratory limb. Because the two limbs touched, the inspiratory limb melted and a leaky hole was created in the circuit. The expiratory limb also melted but did not have a hole.

The breathing circuit should be equipped with a temperature probe away from the Y connector. By connecting the temperature feedback at the Y connector, it can cause the heater to keep heating, since the feedback temperature at the Y always fluctuates due to the temperature change every time the patient breathes in and out.
==========
Manufacturer response for Universal Neonatal Heated Ventilator Breathing Circuit, Hudson RCI
==========
Recommended to replace with a different kind of circuit.

Device 1:
Type: Ventilator
Manufacturer: Newport Medical
Brand: E-500
Model #: E-500

Device 2:
Type: Ventilator
Manufacturer: NEWPORT MEDICAL
Brand: E-500
Model #: E-500

Device 3:
Type: Ventilator
Manufacturer: Newport Medical Instruments, Inc.
Brand: E-500
Model #: E-500
Problem:

Biomed Technician verified ventilator did not have an audio alarm. This happens when the ventilator is connected to our nurse call system. When the ventilator cable is plugged to the nurse call system, the nurse call system alarms and is unable to be reset. To reset the nurse call system, the biomed technician has to unplug the ventilator cable from the nurse call system. The ventilator-nurse call alarm board is locked and the ventilator has to be turned off. The RT has to bag the patient twice for 4 minutes to allow the ventilator to reset while it's off. The ventilator is then powered on again and subsequently reattached to the nurse call system.

CARDIOVASCULAR

Device:
Type: Catheter, Percutaneous, Slitter
Manufacturer: Medtronic Inc.
Brand: Attain Command
Model #: 6230UNI

Problem:

The new disposable Medtronic slitter pulled out the lead wire from the coronary sinus during a lead implantation. This event has happened two other times with other physicians since hospital started using this product this year. A new kit was used and the lead was successfully implanted. There was no patient injury identified. The manufacturer replaced the newly disposable slitters with the original universal slitters and will provide additional training. It was noted by the healthcare provider that the slitter handle in the new product is larger than the previous model.

Device:
Type: Ablation Console
Manufacturer: Cryocath Technologies, Inc.

Brand: Ablation Console
Model #: 10000003

Problem:

Attempted to use cryoabation on Ventricular Tachycardiac (VT) pt. System gave high refrigerant flow error. Cryocath umbilical cord and catheter exchanged, troubleshooting and error message remained. Unit remained on for a total of approx 25 minutes and continued to give error message when ablation was attempted. Unit was replaced with cryocath unit from Peds Dept and ablation was successfully administered after approx 1 min of warm-up time. Case delayed approx 30 minutes.
==========
Manufacturer response for Ablation unit, Ablation unit
==========
Device Tested by vendor but could not reproduce problem. Replaced the Valve board and the proportional valve responsible for refrigerant delivery in case there is an intermittent problem. Console is working properly and no problems detected.

Device:
Type: Electrode, Ecg, Monitoring
Manufacturer: 3M Healthcare
Brand: Red Dot
Model #: 2560
Lot #: 2009-09 CU
Cat #: 2560

Problem:

Nursing staff reported difficulty in obtaining good clear ECG signal including heart and respiration rates. Biomed discovered that the electrodes in use were very dry. Further investigation of unopened packages in the warehouse led to the suspicion of a faulty lot of electrodes from the manufacturer. The electrodes were not expired, and even unopened packs contained electrodes that were very dry and peeled away from the backing easily.

Sales representative from 3M came on the next business day and confirmed that the electrodes were defective but this was not a problem that 3M had been aware of previously. 3M provided replacement product.

Device:
Type: Lead, Pacemaker, Temporary
Manufacturer: Ethicon Inc.
Brand: Temporary Pacing Wire
Cat #: TPW 50
Problem:

The patient had a CABG X 4 and pacer wires were placed at the time. On post-op day 6

in anticipation of discharging the patient, the Physician Assistant (PA) pulled the wires. The patient appeared to seize followed by a full code arrest. CPR was administered and the chest was opened in the room. A rhythm was re-established and the patient was taken to the OR. The patient was placed on bypass. A laceration of the right coronary vein graft was repaired. The graft was lacerated by a clip that was holding the pacer wire to the right atrium. The patient was discharged to an acute rehab facility post-op day 17. He had problems with speech. He was impulsive and required verbal cues to respond to commands appropriately.

GASTROENTEOLOGY & UROLOGY

Device:
Type: Lap-band, Gastric
Manufacturer: Allergan, Inc.
Brand: Aps Access Port Lap-band System
Model #: B-2240

Problem:

Patient required replacement of lap band due to leakage in the actual band portion, which inflates with saline to resemble an inner tube. Upon removal of entire system, surgeon examined the band again by putting fluid into the system. There was an obvious leak coming from the band. The band was placed approximately 21 months ago.

Device:
Type: Valve, Stopcock, Nasogastric
Manufacturer: Bard Medical Division
Brand: Lopez Valve-adult
Lot #: NGSL0041
Cat #: 0056000

Problem:

Nursing staff report that they are experiencing a possible misconnection with the Adult Lopez Valve and nasogastric (NG) tubing. The universal adaptor on the Lopez Valve is designed to fit onto side "A" of the valve device. However, it easily fits onto side "B" as well. If the adaptor is placed on side B (the wrong side), then staff report that the NG tube leaks because it does not have as secure of a fitting due to the tapered side B tip. Instructions on the device packaging are clear.

Staff feels that the device could be improved if the universal adapter was not removable or if it was a different size such that a possible misconnection could not be made.
==========
Manufacturer response for NG valve, Lopez valve--adult

==========
Information contained in this report has been faxed to the manufacturer.

Device:
Type: Nasogastric Tube
Manufacturer: Covidien Kendall
Brand: Kendall Argyle Salem Sump
Model #: 8888264986

Problem:

After inserting the nasogastric tube, the nurse attempted to check the placement. The nurse was unable to do so. The nasogastric tube was removed and it was discovered there were no openings at the distal end of the tube. A new nasogastric tube was then inserted.

Device:
Type: Dialyzer, Hemodialysis
Manufacturer: Fresenius Medical Care North America
Lot #: 8NU803
Cat #: F180NR

Problem:

Small amount of blood found on the floor. Blood found leaking from venous end of dialyzer. Treatment paused and only arterial blood returned. Approximately 200 cc of normal saline with blood was lost. New system was set up, and treatment was resumed after ten minutes.

Device:
Type: Catheter, Retention, Barium Enema With Bag
Manufacturer: Medline
Brand: Bag, Enema Flip Top Dry
Cat #: DYND70102

Problem:

Patient told Risk Management gave himself the enema. He left the cap on but when he pulled it out, the cap was not on and he told the nurse this. The patient was provided the supplies and instructions. We discovered that the cap was left inside the patient. Cap was extracted in Medical Procedure unit (MPU).

We had a similar report earlier this year.

All of Enema kits from Medline packaging lacks instructions to remove the (dark blue) end cap prior to insertion. We have switched our products from Medline (DYND70102) to MediChoice (ENBG1500), the product from MediChoice has clearer directions.
==========
Manufacturer response for bag, enema flip top dry, bag, enema flip top dry
==========
Working on adding instructions to remove the (dark blue) end cap prior to insertion.

Device:
Type: Catheter, Nephrostomy
Manufacturer: Cook Medical, Inc.
Brand: Ultrathane Mp Mac. Loc Rb 8. 5f 38 25cm 6sh Percutaneous Nephrostomy Tube
Lot #: 2260385
Problem:

A Cook 8.5 French percutaneous nephrostomy catheter was placed successfully. A month later, the patient who was 31 5/7 weeks pregnant experienced increased flank pain and the tube was not draining well. The catheter hub was cut and extensive attempts were made to pass two different wire guides through the tube. Wire passage was not possible secondary to complete obstruction. Attempts were made to remove without a wire. However, the pigtail was completely locked in place. The pigtail was unable to be unlocked. A sheath was placed and the nephrostomy tube straightened. However, the tube would not pass completely into the sheath. Approximately 7mm of the distal tip would not pass into the sheath.

A density consistent with sediment/calcification was noted at the catheter tip. Despite numerous attempts the catheter tip was unable to be removed, and upon final traction with the use of a hemostat the tip of the catheter broke and remained in the retroperitoneal tissue. The plan is to remove the broken tip of the catheter laparoscopically after the delivery of the infant.

EAR, NOSE & THROAT

Device:
Type: Cochlear Implant
Manufacturer: Cochlear Americas
Brand: Nucleus Freedom
Model #: CI24RE
Problem:

Patient is an adolescent with bilateral cochlear implants. His right side was implanted when he was a toddler. His left side was implanted ~3 years ago.

More recently, his older right implant has been functioning poorly for him. It does not provide him with useful sound and makes distracting noises. He notes that last fall, he

began noticing a "bumblebee" bubbling sound in the right cochlear implant. In spite of adjustments to his MAPS, this would not go away. He had his processor upgraded on the right and this did not improve things. He now feels that he cannot tolerate this. He wears his processor so that he does not get in any trouble, but leaves it turned off.

His parents are very frustrated with this. They want him to benefit from both implants. They also feel that there has been a recent decline in his performance in school, which they think might be due to his right implant not being utilized. He underwent integrity tests by Cochlear Corporation ~5 months ago. The test was interpreted as normal.

Recently, the patient came in to have his existing right side device explanted, and replaced with a new one. The device was explanted as defective and sent to Biomedical Engineering.

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Medical Device Problem Summaries

Summary of MedSun Reports Describing Adverse Events With Adjustable Gastric Banding System

Print Item
E–mail Item

The Adjustable Gastric Lap-Band is a surgically implanted device used to help a person loss weight. The system consists of a hollow silicone band, tubing, and an access port. The band is placed around the upper part of the stomach, which creates a small pouch that holds a small amount of food. The narrowed opening between the stomach pouch and the rest of the stomach controls how quickly food passes from the pouch to the lower part of the stomach. Base upon the patient's needs, the band can be inflated or deflated by adding saline through the access port. The access port is placed under the skin in a muscle in the chest wall (1).

Over the past two years, MedSun has received twenty adverse event reports associated with the gastric lap band device manufactured by two manufacturers: Allergan, Inc. and Ethicon Endo-Surgery, Inc. The reports were submitted by fifteen hospitals between June 2007 and June 2009. The problems reported were as follows:

• 9 reports associated with fluid leakage.
• 2 reports that involved out-of-box inflation problems (i.e. device would not inflate when the surgeon tested on the field prior to insertion.
• 2 reports of fracture of device material (port fractured).
• 2 reports that involved erosion.
• 1 report that involved a fragmentation of the band buckle.
• 1 report of slippage

• 1 report of failure to flush
• 1 report associated with detachment of components
• 1 report of internal/external damage

From the 20 reports received, one report involved a patient death and one listed a patient injury. There were two reports where the device type was not listed. There are 16 reports that mention a device malfunction. The patient injuries listed below were reported in 14 of the 20 reports.

• 13 additional surgical procedures required
• 1 sepsis/peritonitis
• 1 dysphagia
• 1 hospitalization
• 1 abdominal pain
• 1 erosion
• 1perforation of organ
• 1 nicks, cuts or tears of dura or other tissue

Of the reports that listed patient age, none listed patient age as less than 21 years, and 20 reports had a patient age listed as greater than 21 years. Of the reports that listed patient gender, a total of 17 reports involved female patients, and a total of 3 reports involved male patients.

These MedSun reports contributed to FDA awareness of the device problems. FDA continues to investigate these problems. If you have experienced these types of problems, please report them to the FDA.

Summary of MedSun Reports Describing Adverse Events between June 2007 and June 2009 With The Adjustable Gastric Banding System

Device	Device Identifiers	Event Description
Allergan, Inc.	Lap-band Model B-2250	Lap-band device had defective tubing. It was broken and leaked fluid.
Allergan, Inc.	Device Identifiers unknown	Leak in lap-band tubing. The device was removed from patient.
Allergan, Inc.	Device Identifiers	patient with history of morbid obesity with laparoscopic band procedure three or four years ago.

	unknown	Patient lost about 150 pounds. Patient developed severe upper abdominal pain, which brought her to the hospital for a workup. The patient required multiple exams, which included two esophagogastroduodenoscopy procedures. During the second procedure, a retroflexed view of the gastric cardia showed the eroded band visible in the gastric cardia mucosa. The mucosal perforation was noted with the band covering the opening. Twelve days later, the patient underwent laparoscopic surgery for removal of the adjustable gastric band and suture repair of the stomach. Per nursing notes, patient discharged in stable condition.
Allergan,Inc. /Bioenterics Inamed Lap-Band	B-2220, SIZE - 10CM	Inamed Bioenterics adjustable gastric banding lap band placed last year. Initially band was effective and patient was demonstrating good weight loss. Recently, the fluid in the lap band system has been slowly leaking from somewhere in the system with no liquid being in the band on re-checks. The physician felt the likely site of leaking was at the port. Patient was taken to operating room for replacement. Upon mobilizing the port from its facial attachment, it was brought up into the wound. A clamp was used to clamp the tubing distal to the port and then using a huber needle the port was accessed and saline was injected. A leak was immediately identified in the port at the junction between the rubber dome and the white plastic portion of the port. It appeared the port was leaking in this location and losing fluid. No other areas of leakage were identified. The port was removed and replaced with a new port. The new port was then accessed with a huber needle, saline was injected and it was determined port was watertight and holding the fluid with no problems.
Allergan, Inc./Inamed	Device Identifiers Unknown	Patient had lap band placed earlier this year. Patient returned for replacement of original lap band due to leak in band. Band would not retain saline. Upon removal the leak was noted to be in the actual band portion, not the port or tubing. Entire system replaced with new system.
Allergan, Inc./APS Access Port Lap-Band System	B-2240	Patient required replacement of lap band due to leakage in the actual band portion, which inflates with saline to resemble an inner tube. Upon removal of entire system, surgeon examined the band again by putting fluid into the system. There was an obvious leak coming from the

		band. The band was placed approximately 21 months ago.
Allergan, Inc. /Lap-band	Device Identifiers Unknown	Port was tested and it failed because it was unable to flush fluid.
Allergan, Inc./Lap-band system vg with access port II low profile	Device Identifiers Unknown	Patient who had a lap-band placed earlier in the year had numerous adjustments for the lap-band. Patient noticed there was no limit to her satiety that had been present after initial surgery and she was gaining weight. She could eat large amounts and knew that was not normal. Surgeon suspected a malfunctioning port. It was not holding pressure and was recently replaced with a new lap-band port because of port leakage. The surgeon examined the old port, and clamped the tubing on the old port. He placed fluid into the port under pressure, and could see fluid leaking from the septum of the port. The port was saved.
Allergan, Inc. /Innerdyne Regular	Device Identifiers Unknown	There were no complications after surgery or subsequently, but then patient died a few weeks later from sudden onset of "sepsis due to peritonitis with ascites due to beta streptococcus group a wound infection," according to the autopsy report.
Ethicon Endo-Surgery, Inc. /Realize	Device Identifiers Unknown	The patient was status post gastric banding. He had received one 4 cc fill previously. During the fill attempt three months after banding, the physician was able to access the port w/o difficulty. He instilled 2.5 cc of saline with a bit of restriction to the fluid. He then could not withdraw saline after the instillation. Two other attempts were made with the same results. Fluoroscopic challenge was made at a later date; it revealed extravasation at the neck of the port. Subsequently, the patient underwent laparoscopic port replacement.
Allergan, Inc. /Lap-band Sytem	Device Identifiers Unknown	A gastric band that had been implanted for over a year leaked and would not retain the saline that was injected for restriction. The leak was in the tubing about 10 cm from the band itself, which could not have been caused by the patient or the surgeon.
Allergan, Inc. /Lap-band	B2220	The patient was one year and four months out from laparoscopic adjustable gastric banding. The band demonstrated lack of restriction and was believed to have a slow leak. The physician took the patient to the operating room to remove the band.

Ethicon Endo-Surgery, Inc. /Realize	Device Identifiers Unknown	Patient was having dysphagia and pain. Patient had gallbladder surgery, and surgeon examined band site. Erosion identified and band was removed. The clear soft plastic to keep the device from cracking at the hub came away from the catheter, and slid down the catheter.
Allergan, Inc. /Calibration tube	Device Identifiers Unknown	We applied the stapler across initially, and then applied it again, this time we encountered a hard structure. It turned out to be a calibration tube which is a lap band-type tube which was placed by anesthesia in error. The stapler actually cut through part of the tip of the calibration tube. We had to open this area, and remove the remaining pieces of the calibration tube from the abdominal cavity. A portion of the staples had pierced the tube itself. Once this was done, it left an opening in the gastric pouch as well as the rim of the stomach and these were both repaired with the stapler. This is from the operative note.
Allergan, Inc.	Device Identifiers Unknown	A needle was inserted into the left upper quadrant beneath the costal margin in the midclavicular line. The abdomen was then insufflated with approximately 4 l of carbon dioxide with pressures not to exceed 17 mm Hg. Next, an 11-mm transverse incision was made approximately 2 cm superior and 2 cm to the left of the umbilicus. An 11-mm trocar and portal were inserted. The trocar was removed. The portal was connected to the insufflator. A light and video camera were connected to a 10-mm angled diagnostic laparoscope. At this point, it was felt that the anterio-posterior large lap-band would be the appropriate size. The lap-band was now introduced into the abdominal cavity using the band introducer through the 15-mm portal without difficulty. Attention was now focused on the 15-mm right upper quadrant port site. This incision was lengthened medially and laterally. At this point, we noted a small band fragment at the level of the fascia. This was approximately 5 mm x 2 mm x 0.5 mm in size. It was elected to reinsert the ports and inspect the band itself. Upon inspecting the band itself, there was noted to be a very small fragment of the leading shoulder to the buckle of the band with no other band injury. There was no apparent injury to the band itself. The cuff was now inflated under pressure, and 15 ml of fluid was added to the cuff with no apparent leak. These findings were discussed by telephone with

		technical representatives of the brand manufacturer, Allergan. Following discussion and further inspection of the band, it was felt that the integrity of the tubing band and cuff was intact. It was felt that there was a small fragment of the buckle missing. However, this did not affect the integrity of the buckle itself, and that we could safely leave the band in its present location. Pictures of this defect were made prior to removing the laparoscope and port.
Allergan, Inc. / Lap-band	B2240	Allergan lap-band port fractured and had to be replaced with another lap-band by Allergan. The initial lap-band placement procedure was done at another facility.
Allergan, Inc. /Bioenterics Lap-band	B-2250	When surgeon was testing the lap-band on the surgical field prior to insertion it would not inflate. The item was not used. Another lap-band was opened and used successfully.
Allergan, Inc. /Inamed Lap-Band System	B2220	Patient had laparoscopic gastric banding done last year. The band failed and caused a leak. The patient had the band removed six months later and replaced with same type of implant.
Allergan, Inc. /Inamed Lap-Band System	B2220	Lap-band "slipped." Initially, the lap-band was implanted a few years ago. The lap-band was removed and a new lap-band was implanted from the same manufacturer.
Allergan, Inc. /Lap-Band AP System	Device Identifiers Unknown	The lap-band device broke apart in two pieces when placing around stomach per doctor.

Additional Information:

1. LAP-BAND® Adjustable Gastric Banding (LAGB®) System - P000008. Online Available: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm088965.htm[45]